

High-resolution colon manometry in patients suffering from LARS symptoms after surgery for rectal cancer.

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Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	Gastrointestinal neoplasms malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON28500

Source

NTR

Brief title

TBA

Condition

- Gastrointestinal neoplasms malignant and unspecified

Synonym

rectal cancer

Health condition

rectal cancer, low anterior resection syndrome, LARS, fecal incontinence, fecal urgency, frequency, fragmented defecation, soiling, bowel symptoms

Research involving

Human

Sponsors and support

Primary sponsor: Flanders Research Foundation

Source(s) of monetary or material Support: FWO (Fonds Wetenschappelijk Onderzoek)

Intervention

- Medical device

Explanation

Outcome measures

Primary outcome

Evaluation of the motor patterns characteristics and the discrepancy in occurrence of sequences in patients with major LARS versus patient with no or minor LARS.

Secondary outcome

Description of the relation between colonic motor patterns and propulsion as well as description of the relation between colonic motor patterns and symptoms.

Study description

Background summary

Survival rates after rectal cancer and oncological outcomes have improved significantly over the years. Improved imaging, neoadjuvant therapy and standardized surgery all add to an improved oncological outcome. Radical surgery - a total mesorectal excision (TME) - remains the gold standard treatment. Because of the excision of the rectum, the rectal reservoir as such is lost. As a consequence, a low anterior resection - although nerve- and sphincter sparing - may result in debilitating functional consequences concerning bowel function. These bowel symptoms are commonly referred to as the Low Anterior Resection Syndrome (LARS); a complex syndrome consisting of a multitude of possible bowel symptoms, with consequences for the patient's quality of life.

Notwithstanding the overwhelming use of 'LARS' as a term to describe these bowel symptoms (such as: incontinence for flatus or feces, frequent bowel movements, urgency and clustering of defecation), the exact pathophysiological mechanisms still remain poorly understood. It is hypothesized that the etiology of LARS is multifactorial, and relates to neo-rectal capacity and compliance, sphincter function, pelvic floor function, colonic motility and postprandial response. Based on these hypotheses, first it was explored if the creation of a rectal neo-reservoir would prevent LARS. However, evidence shows that a rectal neo-reservoir does not contribute to long term differences concerning bowel complaints,

questioning its contribution to LARS/postoperative bowel function. However, the creation of a neo-rectum has been suggested to delay motility patterns; i.e. when stool reached the rectum, a delay of defecation was observed. Second, it has been demonstrated that, along with TME, a high ligation of the inferior mesenteric artery and the inferior mesenteric vein at the inferior border of the pancreas, could result in altered colonic motility and consequently affect postoperative function (LARS) due to autonomic denervation. To our knowledge, the impact of the mechanisms associated with radical surgery on colonic motility has only been scarcely investigated. Therefore, the innovative technique of high-resolution colon manometry (HRCM) can provide valuable insights into colonic motility patterns. Recently, a consensus statement on terminology and definitions of these patterns was published, giving an overview of the current knowledge. A recent study of Keane et al. using HRCM, demonstrated that in patients who underwent distal colorectal resection (on average 6.8 years before), LARS was associated with altered colonic motility.

Study objective

The rationale of this study was to investigate the alteration of colonic motor patterns in the early postoperative stage and between patients with no or minor LARS-symptoms (LARS-score < 30) compared to patients experiencing major LARS complaints (LARS-score $\geq$ 30). Consequently, the aim of this study was to investigate colonic motor patterns with HRCM and to assess the effect of hindgut denervation on the presence of coordinated proximal to distal contractions in rectal cancer patients suffering from varying degrees of LARS after TME.

Study design

The morning after an overnight fast of no less than 12 h, subjects were expected at the endoscopy unit of the University Hospitals of Leuven. Loperamide hydrochloride was discontinued for 1 day. Bowel preparation consisted of one-liter of water enemas (Moviprep) at two timepoints the day before the HRCM. The colonoscopy was performed under conscious sedation (up to 5 mg midazolam). A high-resolution manometry (HRM) catheter (10-F solid state catheter containing 40 pressure sensors spaced 2.5 cm apart, Unisensor AG,) was clipped into the mucosa of the caecum. Two hours later, subjects were positioned in a semi-recumbent pose on a bed and colonic pressure recordings started for 3 h. The subject subsequently received a standardized meal, based on the habitual Belgian lunch, and the recording of colonic pressures continued for two more hours. At this point, bisacodyl (10 mg) was administered intraluminally, thereafter, pressure recording continued for a maximum of 1 h. When the measurement was finished, the HRM was removed with a gentle pull.

Intervention

High resolution colon manometry

Contacts

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Eligibility criteria

Age

Adults (18-64 years)
Adults (18-64 years)
Elderly (65 years and older)
Elderly (65 years and older)

Inclusion criteria

(i) patients who had a LAR, with TME for rectal cancer, (ii) patients have to be disease-free at time of inclusion (minimally 10 months after surgery) (iii) patients who are able to come to UZ Gasthuisberg (UZ-GHB) for one complete day

Exclusion criteria

(i) had a Hartmann procedure, abdominoperineal excision, transanal endoscopic microsurgical resection, or sigmoid resection, (ii) were incontinent for feces before surgery, and (iii) already had previous pelvic surgery, previous pelvic radiation or LAR for non-cancer reasons

Study design

Design

Study phase:	4
Study type:	Observational non invasive
Intervention model:	Single
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown
Primary purpose:	Diagnostic

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	19-02-2019
Enrollment:	18
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable	
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register ID

NTR-new NL7737

Other the Ethical Committee of the University Hospitals of Leuven : S61398

Study results

Results posted: 06-03-2024

Actual enrolment: 18

Summary results

"Although references to the 'Low Anterior Resection Syndrome' (LARS) are omnipresent, the exact pathophysiological mechanisms continue to be an enigma to date. Consequently, for this study, we utilized the state-of-the-art technique of high-resolution colon manometry to explore colonic motor patterns in patients who suffered from varying degrees of LARS. One to two years after restoration of transit, patients after TME were asked to enter the

study protocol and undergo high-resolution colon manometry. Colonic motor patterns were analysed and occurrences were compared between nine patients with major LARS and nine patients with no/minor LARS. A differentiation between six different colonic motor patterns was made: (1) + (2) short single propagating motor pattern (antegrade/retrograde), (3) + (4) long single propagating motor pattern (antegrade/retrograde), (5) simultaneous pressure wave and (6) high amplitude propagating contraction (HAPC). Furthermore, the relationship of the motor patterns with the LARS-scores was investigated. Results demonstrated that patients with major LARS showed significantly more cyclic short antegrade motor patterns overall, as well as post-bisacodyl (= a laxative) administration. This type of pattern also showed to be strongly correlated to the LARS-scores. Regarding other patterns, no other significant correlations were found with the LARS-scores. HAPC's only occurred after the administration of bisacodyl in every patient. Finally, patients with major LARS displayed significantly less HAPC's that started in the proximal colon and ended in the mid-section of the colon, compared to patients with no/minor LARS."

Baseline characteristics

Between 12 and 24 months after TME/stoma closure, 19 patients were included: nine patients with a LARS- score below 30 (no/minor LARS, range = 11- 29) and ten patients with a LARS-score higher or equal

Participant flow

Of all contacted patients (n= 26), 21% declined/were not able to come to the hospital for a full day, 7% could not be reached and in 4%, there was a language barrier.

Adverse events

One patient with major LARS experienced a serious adverse event (SAE; acute fever, nausea, vom-iting; not related to the measurement) and could not complete the measurement (no bisacodyl was administered). This pat

First publication

10-06-2022

URL result

Type

ext

Naam

PubMed

URL